

CLEMENT K.
JONES, MD

2100 WEBSTER
SUITE 331
SAN FRANCISCO
CA 94115
415.563.NECK(6325)
FAX 415.923.5896
EMAIL spinectr@spinenet.com

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Document Management Branch
(HFA-305)
Food & Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

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RE: Docket #97N-484S

To Whom it may concern:

I was previously made aware of a submitted proposal to require FDA regulation and approval of some types of bone allograft as medical devices. The original proposal was spearheaded by a spinal implant-manufacturing firm which was required to (successfully) endure FDA premarket requirements and/or FDA-sponsored clinical trials and lengthy regulatory documentation.

The idea and suggestion that certain or selective allograft bone tissues and bone banks be reclassified into a class III status is nothing short of stupid. Allograft bone tissues have been in frequent clinical use for nearly 50 years or more. Reclassification of allograft bone would be inappropriate, wasteful and ludicrous. The fact that certain allograft bone tissues are "machined" to facilitate specific and precise insertion and improved clinical results does not necessitate reclassification into the same category as other nonbone devices for which there is no pre-existing base of information of safety and efficacy. In fact, the FDA has already deemed bone products as "proven safe and efficacious" and without need for further study or regulation-much like crutches, plaster-of-Paris casting material, or, implantable joint prosthetics.

The economic impact of any new regulation of allograft bone is far reaching and staggering. In my own practice of orthopedic and spinal surgery, usage of allograft bone products is extensive. If these products required more regulation their resultant lack of availability and inflated cost would deprive patients and the general public of the quality of healthcare delivery to which they are entitled.

I implore any lay or medical participant in this review process to realize the unnecessary burden and adverse economic impact that the proposals would have. I would recommend that the proposal to regulate some types of bone allograft as medical devices be completely dismissed.

Sincerely,


Clement K. Jones, M.D.

CKJ:dm

cc: Ron Pickard

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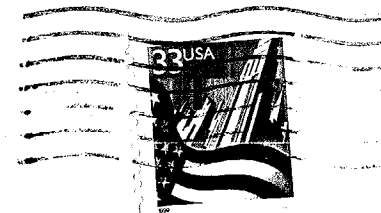
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20857+0001

